U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

RESEARCH INVOLVING HUMAN SUBJECTS

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By Order of the Acting Assistant Director
Stewart D. Smith, DHSc/s/

1. **PURPOSE.** The purpose of this issuance is to set forth the policy and procedure for the review and approval of human subject research.

2. **APPLICABILITY:** This policy applies to all IHSC personnel (including, but not limited to, Public Health Service (PHS) officers, employees, and federal contractors) assigned to IHSC-staffed facilities supporting health care operations in ICE owned or contracted detention facilities, and to IHSC Headquarters staff.

3. **AUTHORITY:** The relevant laws and regulations pertaining to the medical care of persons detained by the U.S. Immigration and Customs Enforcement (ICE) provide the authority to establish policy and management practices for this issuance. The Secretary of the Department of Homeland Security (DHS) exercises the ultimate authority and responsibility for DHS with respect to ensuring the safety and protection of human subjects in research conducted or sponsored by DHS. The Under Secretary for Science and Technology is designated by the Secretary as the DHS Human Subjects Protection Official (HSPO) and has the authority to fulfill the Secretary's objectives by ensuring that DHS fully understands, implements, and complies with both the letter and the spirit of the Common Rule, and any other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted or supported by DHS.

   a. 45 CFR Part 46, Protection of Human Subjects;

   b. Department of Homeland Security Management Directive 026-04, Protection of Human Subjects;

   c. Paperwork Reduction Act (PRA) of 1995, as amended, 44 U.S.C. § 3501–3520;

d. Privacy Act of 1974, as amended, 5 U.S.C § 552a;

e. DHS / ICE 013 – Alien Medical Records System of Records Notice; and

f. Department of Homeland Security Management Directive 10500, Research Misconduct

4. POLICY AND PROCEDURES: This policy and the associated procedures apply to all research involving human subjects or information pertaining to human subjects. A request to conduct research will be submitted to the IHSC Epidemiology Branch using the "Research vs. Non-Research Determination Form" (IHSC-110). All research approvals must be accomplished prior to initiation of the project. Non-intervention research will be considered if it is justifiable as generating information important to the ICE mission. Detainees will not be used as subjects in medical, pharmaceutical or cosmetic experiments or intervention research. . Nothing in this policy shall be construed to affect or in any manner modify or limit the requirements set forth in 8 USC §§ 1101 et seq., implementing regulations, or the exercise of prosecutorial discretion. The conduct of research must comply with all other DHS and ICE issuances, including, but not limited to, privacy, handling of personal identifying information and sensitive personal identifying information, confidentiality, records management, forms management, data sharing, and the Paperwork Reduction Act.

4-1 Definitions

a. Research: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some service programs may include research activities.

b. Non-Research: General attributes of non-research include identifying and controlling a health problem or improving a health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the organization; data collected are needed to assess or improve the program or service, the health of the participants or the organization; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

c. Human Subject: Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

d. Institutional Review Board (IRB): IRB means an institutional review board established in accordance with, and for the purposes expressed in, 45 CFR Part 46. An IRB is a committee that performs ethical review of proposed research.

e. IRB Approval: IRB *approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

f. Federal-Wide Assurance: The Federal-Wide Assurance (FWA) is the only type of assurance currently accepted and approved by the Department of Health and Human Services (HHS), Office of Human Research Protection (OHRP). Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

g. System of Records Notification: A System of Records Notification (SORN) is a legally binding, public notice that identifies and documents collection of agency records about individuals, which are called "system of records" under the Privacy Act. SORNs describe the purpose for a system of records, the individuals covered by the system, the types of records in the system, and authorities for sharing information to outside agencies or groups. SORNs are required by the Privacy Act of 1974 and are published in the Federal Register to provide the public an opportunity to comment on them. ICE has published several SORNs describing its records. For certain types of records, ICE's records are covered by DHS department-wide SORNs or Government-wide SORNs.

4-2. Determination of Research vs. Non-Research. Proposed activities involving systematic data collection and analysis to generate knowledge shall be reviewed by the Epidemiology Branch for a determination of research vs. non-research. The IHSC-110 form and a research concept or protocol shall be submitted to the Epidemiology Branch Chief, or designee, for review and response. If the project is determined to be research, all provisions of this issuance are applicable. If the activity is determined to be non-research, policies and procedures specifically addressing human subjects research do not apply.

4-3. Research Involving Human Subjects or their Records. Research, including activities involving information abstracted from health records,

must be authorized by the IHSC Epidemiology Branch and the supervisory chain, and subsequently submitted for Institutional Review Board (IRB) approval by an IRB holding a Federal-wide Assurance, and DHS Science and Technology Directorate approval. All such research is conducted in accordance with all applicable Federal regulations, and DHS policies.

4-4. Research Protocols Involving Human Subjects or their Records. All research activities shall be carefully designed and described in a detailed research protocol. All research protocols that involve human subjects or records pertaining to human subjects must comply with DHS Management Directive 026-04, Protection of Human Subjects, and The Common Rule at 45 CFR Part 46, Subpart A, and the provisions of 45 CFR Part 46, Subparts B, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research; C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (including detainees); and D, Additional Protections for Children Involved as Subjects in Research. Research must comply with all additional provisions for these vulnerable populations as specified in 45 CFR Part 46, including, but not limited to, composition of IRBs, additional duties of IRBs, and permissible research. All human subject research (not otherwise exempt) is accomplished under an Assurance of compliance approved for Federal-wide use by the HHS, Office of Human Research Protections (OHRP).

a. Protocols describing the proposed methodology for conducting the research or evaluation activity should include at least the following sections: 1) introduction or abstract; 2) background (including references); 3) materials and methods, including study population, sample size determination, data collection, data entry, and data analyses; 4) human research protections and confidentiality; 5) informed consent procedures or rationale for requesting a waiver of informed consent; and 6) compliance with criteria for exemption from Federal oversight as specified in 45 CFR 46.101b (if applicable).

b. Determinations of exemption must be made by an appropriate official above the level of the principal investigator and under the provisions of 45 CFR 46.101(b).

c. If multi-agency research is conducted, each entity engaged in research must comply with all applicable regulations and agency policies, unless the research is exempt under 45 CFR 46.101(b). Formal interagency agreements should be considered to establish agreed-upon roles and responsibilities, and to comply with data-sharing requirements not covered under current SORNs.

d. Medical and other records, and information abstracted from existing records, are considered identifiable. Subsequent removal of identifiers after data collection and abstraction does not compensate for the availability of identifiers for the purpose of exemption from Federal oversight under 45 CFR 46.

4-5. Ethics Training Requirements. All investigators engaged in research involving human subjects or records pertaining to human subjects must have documentation of an approved training in the ethical conduct of human subjects research. This documentation of completed training is submitted with the research protocol for all required approvals.

4-6. Agency Approvals. All research and evaluation protocols that involve human subjects or records pertaining to human subjects and involve systematic data collection and analysis (quantitative or qualitative) shall be reviewed by the Epidemiology Branch prior to final IRB approval for a determination of research vs. non-research, technical review, ethics considerations, and compliance with Federal regulations and guidance. The Epidemiology Branch Chief, or designee, will make a recommendation to the respective Branch Chief, Deputy Assistant Director, and/or Assistant Director.

All research and evaluation protocols are reviewed and approved through the supervisory chain to the level of the IHSC Assistant Director, prior to submission for Institutional Review Board (IRB) approval.

Documentation of IRB approval shall be submitted to the DHS Human Subjects Protection Officer (HSPO), through the Regulatory Compliance Office (RCO), for final approval in accordance with DHS Management Directive 026-04 and DHS, Science and Technology Directorate, Guidelines for Compliance with and Implementation of Federal Regulations for the Protection of Human Research Subjects. All approvals must be documented and on file before the research activity may begin.

Ongoing research must be reviewed annually by agency officials and by the approving IRB as provided for in 45 CFR 46.

4-7. Institutional Review Board (IRB) Approval. All proposed research involving human subjects is reviewed and approved by an IRB operating under a current Department of Health and Human Services/HHS/Office of Human Research Protections (OHRP) Federal-wide Assurance, unless it has been determined to be exempt under the provisions of 45 CFR 46.101(b) by an appropriate official, above the level of a principal investigator prior to initiating the research activity.

a. Research involving detainees. All proposed research protocols shall be submitted for IRB review under the provisions of 45 CFR Part 46, Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (includes detainees), including, but not limited to, composition of IRBs, additional duties of IRBs, and permissible research.

4-8. Paperwork Reduction Act (PRA) Requirements. Any data collection activity (research or non-research) must comply with the provisions of Paperwork Reduction Act (PRA) of 1995, as amended, 44 U.S.C. § 3501–3520, including clearance by the U.S. Office of Management and Budget (OMB) as provided for in the PRA.

a. Procedure. Procedures regarding compliance with the Paperwork Reduction Act (PRA) of 1995, as amended, 44 U.S.C. § 3501–3520, are described in Department of Homeland Security Management Directive 0555.2, Forms Management; ICE Directive 1-30.0, ICE Forms Management; and the ICE Forms Management Handbook.

4-9. Privacy Act (PA) and Alien Medical Records System of Records Notice (SORN) Requirements. Any collection, use, or dissemination of information contained within a record, as defined by 5 U.S.C. § 552a(a)(4), or a system of records, as defined by 5 U.S.C. § 552a(a)(5), must comply with the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. § 552a.

Any data contained within a record that is stored within the Immigration and Customs Enforcement Medical Records System must comply with the DHS / ICE 013 Alien Medical Records SORN.

4-10. Reporting of Adverse Events and Research Misconduct. All adverse events associated with the conduct of research activities, including breach of confidentiality, are reported through the supervisory chain and to the Epidemiology Branch. Allegations of research misconduct will be reported in accordance with DHS Management Directive 10500, Research Misconduct.

5. HISTORICAL NOTES: This is an annual review and there are no changes.

6. APPLICABLE STANDARDS: 2011 PBNDS, Medical Care

7. **NO PRIVATE RIGHT STATEMENT:** This policy is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.